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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

is likely to cost the country a king's ransom. This is because most of the newer technology, say even for something like respirator masks required by medical staff dealing with highly contagious diseases such as COVID, are covered by patents, thereby increasing their price, he said.

Taking serious note of this, patent experts appealed to the Central Government to use compulsory licensing under Indian Patents Act to ensure availability of patented medical devices, masks and drugs at an affordable price in the country. The Government can exercise compulsory licensing for patents under three sections of IP Act viz Section 92, Section 100, Section 102.

Under Section 92 of IP Act, the Government can declare a national emergency due to COVID and notify the patents in questions after which any person interested in manufacturing the said patent can make an application to the Controller of Patents who can then issue a compulsory license without following the regular procedure of time-consuming hearings. The patentee will be paid a reasonable royalty rate as fixed by the Controller of Patents, said Thikkavarapu.

Under Section 100 of IP Act, the Government can authorize specific companies to use any patents or patent applications for the "purpose of government". Once the Central Government gives such an authorization to Indian companies, they can begin manufacturing while negotiating royalties with the patentees. In case the Central Government or its authorized company fails to reach an agreement with the patentee, it is up to the High Court to fix the reasonable royalty that is payable to the patentee.

Under Section 102 of IP Act, the government can simply acquire the patents in question from the patentees much like it acquires land for public purpose. Once again if the Central Government and the patentee cannot reach an agreement on the cost of the patents, it is up to the High Court to fix the price of the patents.

In each of these cases, the reasonable royalty is to be fixed with the objective of ensuring the widest possible availability of the patented technology at the most reasonable price for Indian consumers, he said.

In the past the United States has used (or threatened to use) 28 USC 1498 in the times of war and public health crisis, such as the Anthrax scare in 2001, to break patents after paying the owners a reasonable royalty. In the context of the present pandemic, countries like Israel and Equador have either invoked or threatened to invoke compulsory licences for patents that covered potential cures, he added.

Given that compulsory licensing or government acquisition is always likely to raise the hackles of our trading partners, the Government can always consider negotiating either bulk public procurement or technology transfer, while waving the sword of more coercive actions as a negotiating tool. It is a known fact that bulk public procurement can massively reduce the price of even patented products. The question however is whether many of these foreign patentees have the manufacturing capacity to cater, in the short run, to the expected demand from India. If they lack capacity they should be encouraged to transfer technology to Indian companies under reasonable royalty agreements, he stated.

In the past, pharmaceutical companies such as Gilead have licensed their drugs to Indian companies at reasonable royalties.

Source: Laxmi Yadav, Pharmabiz, 14.05.2020

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Manufacturers annoyed over arbitrary and unscientific fixing of RDA value for methylcobalamin by FSSAI

Methylcobalamin manufacturers have once again raked up the contentious issue of arbitrarily fixing of Recommended Dietary Allowance (RDA) value for methylcobalamin by Food Safety and Standards Authority of India (FSSAI) which they claim is not based on scientific rationale with reference to a Government Notification dated January 7, 2020.

Methylcobalamin is widely marketed in the country as a drug for chronic neurological disorders with an RDA of 2000 mcg intramasucular but as per FSSAI it is detrimental for patients when used above 1 mcg for prevention and disease management. Name of some widely sold brands are Locopen capsule, Neugaba M 75 capsule, Nervup 500 mcg injection, Nuroz Forte, Nurofine-2500 injection, Actovis 2500 injection, etc.

RDA for methylcobalamin is currently set at 1 microgram (mcg) for neurological disease management by FSSAI based on data provided by Indian Council of Medical Research (ICMR).

Based on the industry correspondence to share technical details on which 1mcg is specified as RDA for methylcobalamin, FSSAI has maintained that RDA for different essential nutrients for Indians are specified by ICMR which also specifies RDA for vitamin B12

(irrespective of its sources such as methylcobalamine or cyanocobalamine) as 1 microgram (mcg).

"Since revision of RDA does not fall under the scope of FSSAI and any such request may be taken up with ICMR rather than with FSSAI. Moreover, it is to mention that usage of single vitamin B12 (methylcobalamin) at higher doses for patients requires diagnosis by a physician and therefore falls under the scope of CDSCO and not FSSAI," it stated.

"Drug authority has allowed 2000 mcg intramuscular as upper limit but nutraceuticals may be allowed at least 500 mcg RDA for prophalytic use in the interest of patients. One mcg of methylcobalamin to manufacture is of no use," explains Ahmedabad based leading pharma consultant Dr Sanjay Agrawal.

A notification was issued on Recommended Dietary Intake on January 7, 2020 where vitamin B12 RDA was considered as 1 mcg without clarifying the tolerable upper limit (TUL) of each vitamin B12 and individual RDA of each type of vitamin B12. The nutraceutical regulations mention that the quantity of nutrients added to the articles of food shall not exceed the RDA as specified by the ICMR and in case such standards are not specified, the standards laid down by international food standards body, namely, Codex Alimentarius Commission, shall apply. This means that manufacturer of methylcobalamim can manufacture it in 1 mcg strength only.

The issue has been festering due to missing information on tolerable upper limit (TUL) of methylcobalamin from the public domain. Methylcobalamin has a history of safe long term use as a therapeutic agent given in high dosage or via intramuscular injection for the treatment of disorders associated with impaired vitamin B12 absorption. Oral or intramuscular dosages between 1-5 mg are used with no supportive evidence of adverse effect. The usual treatment in PA patient is 1 mg administered intramuscular once every 1-3 month and oral dosages of 300 mcg to 1000 mcg daily could also provide adequate treatment.

"One aspect is body requirement and other is the dose which is to be manufactured. The regulatory authority has considered both as one without giving consideration that only a portion of same will be absorbed. 1 mcg methylcobalamin to manufacture is nothing for Indian public which is already suffering from malnutrition. The FSSAI must take into account that when cynocobalamin is taken only in 1/10 portion, it is absorbed by the body therefore RDA value for each type of vitamin B12 must be different. For prophylactic use atleast 500 mcg methylcobalamin must be allowed to manufacture" elaborated Dr Agrawal.

The FSSAI spokesperson said the differences in the bioavailability of two forms namely, cyanocobalamin and methylcobalamin are also insignificant and may not affect RDA which is very surprising. If that is the truth why water and fat soluble vitamins are given different RDA value," pharma consultant Anshu Yadav argued.

It has been learnt that the FSSAI scientific panel and scientific committee has recommended RDA values in vitamins and minerals for various micro-nutrients using reference from ICMR and Codex in this context.

Methylcobalamin is a form of vitamin B12. It can be used to replace levels in patients who don't have enough and may also be used to treat certain conditions such as neuropathy, ALS and certain types of anemia.

Source: Shardul Nautiyal, Pharmabiz, 14.05.2020

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Gilead gives royalty-free licences for Remdesivir to Indian firms

The Coronavirus pandemic has killed over 2,80,000 people globally, and several drugmakers are racing to develop a viable treatment or vaccine to combat the outbreak.

With no other approved treatment for COVID-19, the respiratory illness caused by the novel Coronavirus, interest in Remdesivir has been growing. To this end, Gilead Sciences Inc has signed a non-exclusive licensing pacts with five generic drugmakers to expand the supply of its experimental COVID-19 treatment Remdesivir.

Out of these, three are based in India:

The licenses are royalty-free until the World Health Organisation declares the end of the public health emergency regarding COVID-19, or until a product other than Remdesivir or a vaccine is approved to treat or prevent the disease. The licensees will also set their own prices for the generic product they produce.

Gilead's antiviral drug Remdesivir earlier this month received the US Food and Drug Administration's emergency use authorisation to treat COVID-19 patients.

The said pacts allow the companies to make and sell the drug in 127 countries, enhancing India's leadership in the global pharmacy market.